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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,514

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Linzhao Cheng

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SAN DIEGO, CA 92121-2133

EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/533,514	CHENG, LINZHAO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deborah Crouch	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 34-64 is/are pending in the application.
- 4a) Of the above claim(s) 34-51 and 57-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 52-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Applicant's arguments filed February 19, 2010 have been fully considered but they are not persuasive. The amendment has been entered. 1-30 and 34-64 are pending. Claims 34-51 and 57-64 have been withdrawn from consideration as to a non-elected invention. Claims 1-30 and 52-56 are examined herein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 18, 25 and 56 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thomson et al., Science, 1998, Vol. 282, pp. 1145-1147, IDS filed 1/11/08, AA) for reasons set forth in the office action mailed November 19, 2009.

Thomson teaches isolated hES cells that have a normal, diploid karyotype and are passaged for at least 32 times (page 1144, col.2, line 19 to col. 3, line 5). Thomson clearly state the hES cells lack SSEA1 (page 1146, col. 1, lines 2-6). Further, hES cells inherently express Oct4 as evidenced by (Xu, page 972, col. 2, parag. 1, lines 1-7). Absent results or arguments to the contrary, all hES cells required, as an inherent property, either a feeder cell layer or feeder cell conditioned media, evidence by U.S. PgPub 2005003748 (Mitalipov), see citations below. The claims do not require the presence of the feeder cells, only that the hES cells depend on them for growth. In a side by side comparison, a patentable distinction could not be discerned between the claimed hES cells and those of Thomson. Claims 18, 25 and 56 states "a culture of undifferentiated pluripotential hES cells prepared by," which does not provide a structural alteration to the hES cells. Thus, Thomson anticipates the claimed invention. In the alternative, as the hES cells of the claims and those of Thomson are not patentably distinct, any differences are obvious differences.

Applicant argues Thomson does not teach undifferentiated hES cells that express Oct4, do not express SSEA1 and exhibit dependence on adult human feeder cells. These arguments are not persuasive.

The structural differences argued by applicant between the claimed cells and those of Thomson are all inherent features of Thomson's hES cells. hES cells are feeder dependent; none are solely dependent on human feeder cells versus mouse feeder cells. The requirement seems to be that the feeder cell must be a fibroblast (see

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Richards, IDS filed 1/11/08, Ref. AE, page 934, col. 2, parag. 1 and 2). Thus dependence on human feeders also is an inherent feature of hES cells.

With regard to applicant's arguments regarding *Abbott Laboratories et al*, Fed, Cir., 2009, that process terms in product-by-process claims serve as limitations in determining infringement, the present prosecution is not an infringement hearing. Thus, the holding by the court is not seen as relevant. The requirement stands that applicant needs to show that the method by which the claimed hES cells are made renders the cells structurally different from those known in the art at the time of filing, or in this prosecution, Thomson. Thus, applicant's arguments are not persuasive.

Thus, for the reasons set forth on this record, applicant has failed to distinguish the claimed hES cells from those of Thomson.

Claims 10-17, 19-24, 26-30 and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 2005003748 (Mitalipov) and Thomson et al., Science, 1998, Vol. 282, pp. 1145-1147, IDS filed 1/11/08, AA) in view of WO00/029001 published May 25, 2000 (McIntosh) for reasons set forth in the office action mailed November 19, 2009.

Mitalipov teaches a culture of hES cells on immortalized human skin fibroblasts and method of obtaining an expanded population of undifferentiated pluripotent hES cells comprising culturing the culture (parag. [0050], [0051] and [0146]-[0156]). The fibroblasts are adult feeder cells producing an ES cell-maintaining product of the supportive adult human feeder cells. Mitalipov also teaches the feeder cells can be used to produce conditioned media (parag. [0202]) It is noted the language of the claims does

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not distinguish over Mitalipov. The claim requires the product of the adult human feeder cells to comprise a fraction of conditioned media consisting of biomolecules having a molecular mass greater than about 30 kDa. The conditioned media of Mitalipov, being produced from adult feeder cells, would have such a fraction.. Mitalipov teaches isolating hES cells so cultured for pluripotency markers (parag. [0155]). further, Mitalipov teaches subculturing hES cells on the fibroblast feeder cells (parag. [0154], lines 6-9).

Thomson teaches isolated hES cells that have a normal, diploid karyotype and are passaged for at least 32 times (page 1144, col.2, line 19 to col. 3, line 5). Thomson further teaches the cryopreservation of hES cells, and subsequently thawing and culturing the frozen cells to create a cell line (page 1144, col. 2, lines 19-22).

The cultures of Mitalipov and Thomson are suspension cultures and contain an hES cell-maintaining product of the feeder cells. Applicant should note the alternative language in claim 52 does not limit the claims to "absence of feeder cells."

McIntosh teaches fibroblast cell line 1087sk, ATCC CRL-2104 (page 11, lines 20-22). McIntosh further teaches the media from culturing the 1087sk cells was used to prepare conditioned media (page 13, lines 3-7).

Thus, at the time of the instant invention, it would have been obvious to prepare a culture of hES cells with conditioned media prepared from CCD-1087sk adult human fibroblasts from breast, culture the culture, subculture the culture and isolate hES cells from the culture as taught by Mitalipov including the teaching the propagation of hES cells on skin fibroblast feeder cells and Thompson including teaching the culture of hES

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cells on mouse embryonic fibroblast cells, in view of McIntosh teaching CCD-1087sk human adult fibroblasts. The artisan would have known at the time of filing to obtain CCD-1087sk cells from the ATCC. The claims require growth on CCD-1087sk feeder cells. The claimed invention is a known method modified by an element from a known and predictable method.

Applicant argues Mitalipov does not teach the hES cell maintaining produce is a product of human adult feeder cells and comprises a fraction of conditioned medium consisting of biomolecules having a molecular mass greater than about 30 kDa. This argument is not persuasive.

As stated above, Mitalipov teaches preparing conditioned media from adult feeder cells. Such media would inherently contain a fraction consisting of biomolecules having a molecular mass greater than about 30 kDa. Applicant needs to alter the language of the claims to indicate product contains only the 30 kDa fraction of conditioned media, if this is the intention of the presently amended claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/



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Primary Examiner, Art Unit 1632

May 8, 2010